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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Sadanobu Shirai

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WENDEROTH, LIND & PONACK, L.L.P.

1030 15th Street, N.W.,

Suite 400 East

Washington, DC 20005-1503

EXAMINER

MERCIER, MELISSA S

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

05/20/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com

coa@wenderoth.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,932	<b>Applicant(s)</b> SHIRAI, SADANOBU	
	<b>Examiner</b> MELISSA S. MERCIER	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-8, 10-12, 16-20 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) 3, 7, 10, 12, 17, 18, 20, 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 6, 8, 11, 16, 19, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12-10, 09, 2-3-10, 4-28-10</u> .                              | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Summary***

Receipt of Applicants Remarks and Amended Claims filed on March 5, 2010 is acknowledged.

Claims 1-3, 5-8, 10-12, 16-20, and 22-25 remain pending in this application. Newly submitted claim 25 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims under prosecution in this application are drawn to a cataplasm and not a method of making the cataplasm. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 25 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 3, 7, 10, 12, 17-18, 20, and 24 additionally remain withdrawn from consideration as reading on non elected species. Therefore, Claims 1-2, 5-6, 8, 11, 16, 19, 22-23 remain under prosecution in this application.

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Applicants request for an interview is acknowledged. However, due to time constraints, an interview was not able to occur prior to this office action. It is suggested that as soon as Applicant has had the opportunity to review this office action and prior to filing a response, Applicant contact the Examiner by telephone and schedule an interview to discuss any issues remaining.

***Information Disclosure Statement***

Receipt of the Information Disclosure Statements filed December 10, 2009, February 3, 2010, and April 28, 2010 is acknowledged. Signed copies are attached to this office action.

***Maintained Rejections***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5-6, 8, 11, 16, 19, and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mooney et al. (US Patent 5,814,031) in view of Muta et al. (US Patent 6,432,431).

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Mooney discloses a structured occlusive dressing. The dressing can be applied directly to a wound, or may be coated directly onto a film or fiber substrate which is, in turn applied to the wound and surrounding skin (column 2, lines 16-36).

The films may be composed of one or more polymers including polyethylene (column 6, lines 22-29), which is a soft plastic resin and the specific resin of claims 6, and 14-16.

The dressings may also be coated onto a fiber substrate which, in turn, is adhesively or otherwise attached to a film substrate. As discussed previously, the claims are drawn to a product prepared by a particular process; patentability is based on the final product. Applicant is invited to present evidence as to the criticality of the heat fusing means of attachment if it results in a different product being formed.

Mooney discloses fiber substrates including fabrics that are knitted such as modified entangled fiber composed of rayon polyesters, such as 90:10 polypropylene-rayon blends (column 6, lines 30-41), which is the particular combination disclosed in instant claims 6 and 14-16.

Mooney additionally discloses generic teachings of adhesive surfaces applied to the film (Example 1).

Mooney does not disclose the thickness of the support film being 3-35um. Mooney additionally does not disclose the particular adhesive composition of instant claims, which is:

- a. water
- b. a moisture retaining agent

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- c. polyacrylic acid and/or its salts
- d. a cellulose derivative
- e. a slight soluble polyvalent metal salt
- f. a pH controlling agent

Muta discloses cataplasms comprising a base of the gel patch containing:

- a. 20-70 % by weight water (column 4, lines 60-62),
- b. A moisturizer such as glycerin or propylene glycol can also be added in the amount of 10-60% by weight (column 5, lines 9-16).

c and d (in combination). water soluble polymers including carboxymethylcellulose sodium, hydroxypropyl cellulose, and polyacrylic acid, which are cross linked with an organic or inorganic crosslinking agent. The polymers may be used alone or in combination and are present in the amount of 0.1-30% by weight (column 4, line 63 through columns 5, line 8).

e. the cross linking agents include polyvalent metal compounds such as aluminum hydroxide and dihydroxyaluminium aminoacetate in the amount of 0.0—5% by weight (column 5, lines 22-34).

f. additives, including pH adjusters (column 5, lines 16-19 and 38-40).

Muta does not disclose the amount of pH adjuster employed or the final pH of the gel base, however, Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to

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discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 105 USPQ 233,235 (CCPA 1955).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used the adhesive composition of Muta with the dressing of Mooney since each of the references teach that patches would comprise adhesive layers, for application of compositions to the skin, it would have been obvious to combine these adhesives with the expectation that such a combination would have the desired effectiveness, such as an adhesive composition has an adhesive strength stable over time and exhibits neither bleeding due to phase separation in the base not so called stickiness due to the decrease of the adhesive force of the base.

Applicants attention is drawn to MPEP 2113, regarding Product by Process claims; which recites: “[E]ven though product-by-process claims are limited by and defined by the process; determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a thinner support based on the needs of the device. Mooney discloses the function of the support is to provide a base for maintaining a cover over the wound, therefore, it would have been obvious to the skilled artisan to utilize a thinner or thicker support based on the needs of the device.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues:

**\*the heat fusing of the support provides a materially distinct structure.**

Applicant has not provided evidence of the distinct structural difference between the fusing of the layers through heat versus through an adhesive composition. After a review of the specification, the Examiner was unable to locate any teaching of a distinct structural difference between heat fusing the layers as claimed versus the use of an adhesive as recited in the prior art. Applicant is invited to provide evidence, such as in the form of a side by side comparison of the supports to showing the distinction.

**\*the dressing of Mooney has a porous cover as an essential component.**

It is respectfully submitted that the instant claims do not exclude the presence of such a cover. The claims only limit the particular support and adhesive layer.

**\*Muta discloses cataplasms comprising a base of a gel patch.**

Muta is relied on the teaching of a specific adhesive composition. The skilled artisan would readily recognize that the adhesive disclosed could be used in other bandage systems and retain the same functional properties described.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/  
Examiner, Art Unit 1615

/Carlos A. Azpuru/  
Primary Examiner, Art Unit 1615